

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Stephen R. ASH

Serial No.: 09/143,143

Filed: August 28, 1998

METHOD FOR IRON DELIVERY TO A
PATIENT BY TRANSFER FROM DIALYSATE

Before the Examiner
J. Pak

Group Art Unit 1616

August 20, 2003

RECEIVED
AUG 25 2003
TECH CENTER 1600/2900

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner for Patents
Alexandria, VA 22313

Sir:

Pursuant to the duty of disclosure in accordance with 37 C.F.R. §1.56, Applicant wishes to bring to the attention of the Examiner the patents, publications and/or other information listed on the attached PTO Form 1449 (modified). Copies of cited items are enclosed in accordance with 37 C.F.R. § 1.98. The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in § 1.56(b).

EXPRESS MAIL LABEL NO. EL983134342US Date of Mailing: August 20, 2003

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



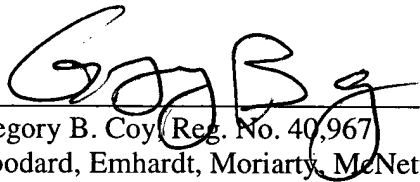
Signature of Person Mailing

It is believed that no fee is required for submission of this IDS because it is being submitted before the mailing of a first Office Action after the filing of a Request for Continued Examination under 37 C.F.R. § 1.114 (see 37 C.F.R. 1.97(b)(4))

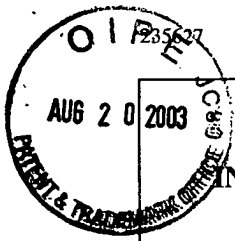
Should any fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

The examiner is invited to contact the undersigned to resolve any matters that will further prosecution of the present case.

Respectfully submitted,



Gregory B. Coy (Reg. No. 40,967)
Woodard, Emhardt, Moriarty, McNett
& Henry LLP
Bank One Center Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456



INFORMATION DISCLOSURE CITATION

Page 1 of 6

ATTY. DOCKET NO.
37011-6

SERIAL NO.
09/143,143

APPLICANT
Ash

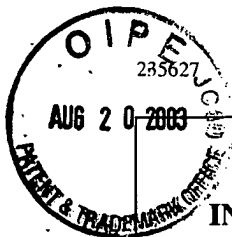
FILING DATE
August 28, 1998

GROUP
1616

U.S. PATENT DOCUMENTS/APPLICATIONS

[illegible]

RECEIVED
AUG 25 2003
TECH CENTER 1600/2900



AUG 25 2003

TECH CENTER 1600/2900

INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO. 37011-6	SERIAL NO. 09/143,143
	APPLICANT Ash	
	FILING DATE August 28, 1998	GROUP 1616

Page 2 of 6

OTHER DOCUMENTS

	Allegra A, Mengozzi G, Vasile A. Iron Deficiency in Maintenance Hemodialysis Patents: Assessment of Diagnosis Criteria and of Three Different Iron Treatments. Nephron 1991: 57:175-182
	Basta, SS, Soekirman MS, Karyadi D, Scrimshaw NS. Iron Deficiency Anemia and the Productivity of Adult Males in Indonesia. The American Journal of Clinical Nutrition 32: April 1979, pp 916-925
	Berner LA, Miller DD, VanCampen D. Availability to Rats of Iron in Ferric Hydroxide Polymers. 1042-1049. Date unknown. (Presented at the 68 th Annual Meeting of the Federation of American Societies for Experimental Biology, April 1-6, 1984, St. Louis, MO.
	Best CH. The Physiological Basis of Medical Practice. The Williams & Wilkins Company, Third Edition, Baltimore, 1943, pp 94-99
	BLUTAL® Injection (Chondroitin sulfate-iron colloid) Product Information. Date unknown.
	Brown EB, Moore CV, Reynafarje C, Smith DE. Intravenously Administered Saccharated Iron Oxide in the Treatment of Hypochromic Anemia. JAMA, Nov. 25, 1950, 1084-1089
	Byrd TF, Horwitz MA. Lactoferrin Inhibits or Promotes Legionella Pneumophila Intracellular Multiplication in Nonactivated and Interferon Gamma-Activated Human Monocytes Depending Upon Its Degree of Iron Saturation. J. Clin. Invest. Vol. 88, October 1991, 1103-1112
	Calvar C, Mata D, Alonso C, Ramos B, Lopez de Novales E. Intravenous Administration of Iron Gluconate During Haemodialysis. Nephrol Dial Transplant (1997) 12: 574-575
	Carver FJ, Frieden E. Factors Affecting the Adenosine Triphosphate Induced Release of Iron from Transferrin. Biochemistry, Vol 17, No 1, 1978 167-172
	Cheuk MS, Loh TT, Hui YV, Keung WM. Kinetics of Pyrophosphate Induced Iron Release From Differic Ovotransferrin. Journal of Inorganic Biochemistry 29, 301-311 (1987)
	Cook, JD, Skikne BS, Baynes RD. Iron Deficiency: The Global Perspective. Progress in Iron Research Edited by C. Hersnko et al. Plenum Press, New York, 1994. pp 219-228
	Ersley AJ. Erythropoietin. NEJM, Vol. 324, No. 19, May 8, 1991. pp 1339-1344
	Eschbach JW, Cook JD, Scribner BH, Finch CA. Iron Balance in Hemodialysis Patients. Annals of Internal Medicine 87: December 1977, 710-713
	Feeley JC, Gorman GW, Weaver RE, Mackel DC, Smith HW. Primary Isolation Media for Legionnaires Disease Bacterium. Journal of Clinical Microbiolog, Sept 1978, Vol. 8, No. 3, p 320-325.
	Fishbane S, Frei GL, Maesaka J. Reduction in Recombinant Human Erythropoietin Doses by the Use of Chronic Intravenous Iron Supplementation. American Journal of Kidney Diseases, Vol 26, No 1, 1995, pp 41-46
	Fishbane S, Lynn RI. The Utility of Zinc Protoporphyrin for Predicting the Need for Intravenous Iron Therapy in Hemodialysis Patients. American Journal of Kidney Diseases, Vol 25, No 3 (March), 1995: pp 426-432



235627

RECEIVED
AUG 25 2003
TECH CENTER 1000/2900

INFORMATION DISCLOSURE CITATION

Page 3 of 6

ATTY. DOCKET NO. 37011-6	SERIAL NO. 09/143,143
APPLICANT Ash	
FILING DATE August 28, 1998	GROUP 1616

	Fishbane S, Ungureanu VD, Maesaka JK, Kaupke CJ, Lim V, Wish J. The Safety of Intravenous Iron Dextran in Hemodialysis Patients. American Journal of Kidney Diseases, Vol 28, No 4 (October), 1996: pp. 529-534
	Fleisch H, Bisaz S. Mechanism of Calcification: Inhibitory Role of Pyrophosphate. Nature, Vol. 195, No. 4844, September 1, 1962, p 911
	Fleisch H. Bisphosphonates – Preclinical. Bisphosphonates in Bone Disease From the Laboratory to the Patient. Second Edition. The Parthenon Publishing Group, Inc. 1995. pp 31-34
	Goetsch AT, Moore CV, Minnich V. Observations on the Effect of Massive Doses of Iron Given Intravenously to Patients With Hypochromic Anemia. From the Department of Internal Medicine, Washington University School of Medicine, St. Louis. Date Unknown.
	Hamstra RD, Block MH, Schocket AL. Intravenous Iron Dextran in Clinical Medicine. JAMA, May 2, 1980, Vol 243, No. 17, 1726-1731
	Harken AH, Simson MB, Haselgrove J, Wetstein L, Harden III WR, Barlow CH. Early Ischemia After Complete Coronary Ligation In The Rabbit, Dog, Pig and Monkey. Am J Physiol 241 (Haert Circ Physiol 10): H202-H210, 1981.
	Harrett RF, Furness DE, Burn J, Whittaker P, Lanen JR, Cook JD. Am J Clin Nutr. (1989):49:1274-82.
	Hatton RC, Portales IT, Finlay A, Ross EA. Removal of Iron Dextran by Hemodialysis: An In Vitro Study. American Journal of Kidney Diseases, Vol 26, No 2 (August), 1995: pp 327-330
	Heath CW, Strauss MB, Castle WB. Quantitative Aspects of Iron Deficiency in Hypochromic Anemia. From the Thorndike Memorial Laboratory, Second and Fourth Medical Services (Harvard Medical School, Boston) Date Unknown (received for publication August 1, 1932).
	Ifudu O, Feldman J, Friedman EA. The Intensity of Hemodialysis and the Response to Erythropoietin in Patients With End-Stage Renal Disease. NEJM, February 15, 1996, pp 420-425
	Jacobs K, Shoemaker C, Rudersdorf R, Neill SD, Kaufman RJ, Mufson A, Seehra J, Jones SS, Hewick R, Fritsch EF, Kawakita M, Shimizu T, Miyake T. Isolation and Characterization of Genomic and cDNA Clones of Human Erythropoietin. Nature, Vol. 313, 28 February 1985, pp 806-810
	Javaid H, Haschke F, Pietschnig B, Schuster E, Huemer, Shebaz A, Ganesh P, Steffan I, Hurrel R, Secretin MC. Interactions Between Infections, Malnutrition and Ironnutritional Status in Pakistani Infants. Acta Prediatr Scand Suppl 374:141,1991
	Jung A, Russell RGG, Bisaz S, Morgan DB, Fleisch H. Fate of Intravenously Injected Pyrophosphate- ³² P in Dogs. American Journal of Physiology, Vol 218, No 6, June 1970, pp 1757-1764
	Kleiner MJ, Van Wyck DB, Kaupke CJ, Kirlin LF. The Role of Iron and Other Factors in Patients Unresponsive to Erythropoietin Therapy. Seminars in Dialysis, Vol. 8, No. 1 (Jan-Feb) 1995 pp 29-34
	Kolff WJ. First Clinical Experience With the Artificial Kidney. Annals of Internal Medicine, Vol. 62, No 3, March 1965, pp 608-619

RECEIVED
AUG 25 2003
TECH CENTER 1600/2903



INFORMATION DISCLOSURE CITATION

Page 4 of 6

ATTY. DOCKET NO. 37011-6	SERIAL NO. 09/143,143
APPLICANT Ash	
FILING DATE August 28, 1998	GROUP 1616

	Konopka K, Mareschal JC, Crichton RR. Iron Transfer From Transferrin to Ferritin Mediated by Polyphosphate Compounds. Biochemica et Biophysica Acta. 677 (1981) 417-423
	Konopka K, Mareschal JC, Crichton RR. Iron Transfer From Transferrin To Ferritin Mediated By Pyrophosphate. Biochemical and Biophysical Research Communications, Vol. 96, No. 3, 1980, pp 1408-1413
	Kornberg A. On The Metabolic Significance of Phosphorolytic And Pyrophosphorolytic Reactions. pp 251-264 Date unknown
	Kumpf VJ, Holland EG. Parenteral Iron Dextran Therapy. DICP, The Annals of Pharmacotherapy, 1990: February, Vol. 24, pp 162-166
	Levin NW. Quality of Life and Hematocrit Level. American Journal of Kidney Diseases, Vol XX, No 1, Suppl 1 (July), 1992: pp 16-20
	Lieberman E, Ryan KJ, Monson RR, Schoenbaum SC. Association of Maternal Hematocrit With Premature Labor. Am J Obstet Gynecol, July 1988, pp 107-114
	Lozoff B, Jimenez E, Wolf AW. Long-Term Developmental Outcome of Infants With Iron Deficiency. N Engl J Med, 1991, Vol. 325, No. 10, pp 687-694
	Macdougall IC, Hutton RD, Cavill I, Coles GA, Williams JD. Poor Response to Treatment of Renal Anaemia with Erythropoietin Corrected by Iron Given Intravenously. Br Med J 1989;299:157-158
	Macdougall IC, Cavill I, Hulme B, Bain B, McGregor E, McKay P, Sanders E, Coles GA, Williams JD. Detection of Functional Iron Deficiency During Erythropoietin Treatment: A New Approach. BMJ, Vol 304, 25 January 1992. Pp 225-226
	Macdougall IC, Tucker B, Thompson J, Baker LRJ, Raine AEG. A Randomised Controlled Study of Iron Supplementation in Patients Treated With Erythropoietin. Date unknown.
	Maurer AH, Knight LC, Siegel JA, Elfenbein IB, Adler LP. Preliminary Studies on Magnetic Resonance Contrast Enhancement of Acute Myocardial Infarction. Investigative Radiology, February 1990, Vol. 25, pp 153-163
	Moore CV. An Outline of Iron Metabolism. 5-7 Date unknown
	Moore LW, Acchiardo S, Sargent JA, Burk L. Incidence, Causes, and Treatment of Iron Deficiency Anemia in Hemodialysis Patients. Journal of Renal Nutrition, Vol 2, No 3 (July), 1992: pp 105-112
	Morgan EH. Iron Exchange Between Transferrin Molecules Mediated By Phosphate Compounds And Other Cell Metabolites. Biochemica et Biophysica Acta, 499 (1977) 169-177
	Morgan EH. Studies on the Mechanism of Iron Release From Transferrin. Biochemica et Biophysica Acta. 580 (1979) 312-326
	Nilsen R, Effects of calcium on hepatocyte iron uptake from transferrin, iron-pyrophosphate and iron-ascorbate. Date unknown.
	Nilsen T, Romslo I. Pyrophosphate as a Ligand for Delivery of Iron to Isolated Rat-Liver Mitochondria. Biochemica et Biophysica Acta. 766 (1984) 233-239
	Nissim JA. Intravenous Administration of Iron. The Lancet, July 12, 1947. Pp 49-51
	NKF-DOQI Clinical Practice Guidelines for the Treatment of Anemia of Chronic Renal Failure. Supplement To AJKD Vol 80, No 4, Suppl 3, October 1997, pp S194-S240



RECEIVED
AUG 25 2003
TECH CENTER 1600/2900

INFORMATION DISCLOSURE CITATION

Page 5 of 6

ATTY. DOCKET NO. 37011-6	SERIAL NO. 09/143,143
APPLICANT Ash	
FILING DATE August 28, 1998	GROUP 1616

	Nyvad O, Danielsen H, Madsen S. Intravenous Iron-Sucrose Complex to Reduce Epoetin Demand in Dialysis Patients. <i>The Lancet</i> , Vol 344, November 5, 1994. 1305-1306
	Oski FA, Honig AS, Helu B, Howanitz P. Effect of Iron Therapy on Behavior Performance in Nonanemic, Iron-Deficient Infants. <i>PEDIATRICS</i> , Vol. 71, Nos. 6, June 1983, pp 877-880
	Oski FA, Honig AS. The Effects of Therapy on the Developmental Scores of Iron-Deficient Infants. <i>The Journal of PEDIATRICS</i> , January 1978, Vol 92, No 1, pp 21-25
	Pollack S, Vanderhoff G, Lasky F. Iron Removal From Transferrin An Experimental Study. <i>Biochemica et Biophysica Acta</i> . 497 (1977) 481-487
	Pollack S, Weaver J. Guinea Pig and Human Red Cell Hemolysates Release Iron From Transferrin. <i>J. Lab Clin Med</i> , May 1985, 629-634
	Rao DS, Shih MS, Mohini R. Effect of Serum Parathyroid Hormone and Bone Marrow fibrosis on the Response to Erythropoietin in Uremia. <i>N Eng J Med</i> , 1993 Vol 328, No. 3, 171-175
	Ristroph JD, Hedlund KW, Gowda S. Chemically Defined Medium for <i>Legionella Pneumophila</i> Growth. <i>Journal of Clinical Microbiology</i> , Jan. 1981, Vol. 13, pp 115-119
	Rosenlof K, Kivivuori SM, Gronhagen-Riska C, Teppo AM, Slimes MA. Iron Availability is Transiently Improved by Intravenous Iron Medication in Patients on Chronic Hemodialysis. <i>Clinical Nephrology</i> , Vol 43, No 3, 1995, 249-255
	Rubinger D, Friedlaender MM, Silver J, Kopolovic Y, Czaczkes WJ, P MM. Progressive Vascular Calcification With Necrosis of Extremities in Hemodialysis Patients: A Possible Role of Iron Overload. <i>American Journal of Kidney Diseases</i> , Vol VII, No 2 (February), 1986: pp 125-129
	Schaefer RM, Schaefer L. Management of Iron Substitution During r-HuEPO Therapy in Chronic Renal Failure Patients. 71-75. Date unknown.
	Schaefer RM, Schaefer L. The Hypochromic Red Cell: A New Parameter for Monitoring of Iron Supplementation During rhEPO Therapy. <i>J. Perinat. Med</i> . 23 (1995) 83-88
	Schibler D, Russell GG, Fleisch H. Inhibition By Pyrophosphate And Poly-Phosphate of Aortic Calcification Induced by Vitamin D in Rats. <i>Clin. Sci</i> . 363-372 Date Unknown
	Schribner BH, Buri R, Caner JEZ, Hegstrom R, Burnell JM. The Treatment of Chronic Uremia by Means of Intermittent Hemodialysis: A Preliminary Report. 114-122 Date unknown
	Schultinik W, van der Ree, M, Matulesi P, Gross R. Low Compliance With an Iron-Supplementation Program: A Study Among Pregnant Women in Jakarta, Indonesia. <i>Am J Clin Nutr</i> 1993;57:135-9.
	Segasothy M, Fairley KF, Birch DF, Kincaid-Smith P, Intravenous Fe-Gluconate-Na for Iron-Deficient Patents on Hemodialysis. <i>Nephron</i> 1992;60:121, 86-87
	Sepandj F, Jindal K, West M. Hirsch D. Economic Appraisal of Maintenance Parenteral Iron Administration in Treatment of Anaemia in Chronic Haemodialysis Patients. <i>Nephrol Dial Transplant</i> (1996) 11: 319-322
	Stevenson JS, Eckelman WC, Sabocinski PZ, Reba RC, Barron EL, Levin SG. The Toxicity of Sn-Pyrophosphate: Clinical Manifestations Prior to Acute LD ₅₀ <i>Journal of Nuclear Medicine</i> . Vol. 15, No. 4, pp 252-256
	Stockman R. The Treatment of Chlorosis by Iron and Some Other Drugs. <i>The British Medical Journal</i> , April 29, 1893, pp 881-885



235627

INFORMATION DISCLOSURE CITATION

Page 6 of 6

ATTY. DOCKET NO. 37011-6	SERIAL NO. 09/143,143
APPLICANT Ash	
FILING DATE August 28, 1998	GROUP 1616

	Sunder-Plassmann G, Horl WH. Importance of Iron Supply for Erythropoietin Therapy. Nephrol Dial Transplant (1995) 2070-2076
	Sunder-Plassmann G, Horl WH. Safety of Intravenous Injection of Iron Saccharate in Haemodialysis Patients. Nephrol Dial Transplant (1996) 11: 1797-1802
	Tsuji Y, Kambayashi JI, Shiba E, Sakon M, Kawasaki T, Mori T. Effect of Recombinant Human Erythropoietin on Anaemia After Gastrectomy: A Pilot Study. Eur J Surg 1995; 161: 29-33
	Van Wyck DB, Stivelman JC, Ruiz J, Kirlin LF, Katz MA, Ogden DA. Iron Status in Patients Receiving Erythropoietin for Dialysis-Associated Anemia. Kidney International, Vol 35 (1989), pp. 712-716
	Weinberg ED. Iron Withholding: A Defense Against Infection and Neoplasia. Physiological Reviews, Vol. 64, No. 1, January 1984, pp 65-102
	Wingard RL, Parker RA, Ismail N, Hakim RM. Efficacy of Oral Iron Therapy in Patients Receiving Recombinant Human Erythropoietin. American Journal of Kidney Diseases, Vol 25, No 3 (March), 1995: pp 433-439
	Worwood M. Ferritin. Blood Reviews, 259-269 Date unknown
	Zanen, AL, Adriaansen HJ, vanBommel EFH, Posthuma R, deJong GMT. 'Oversaturation' of Transferrin After Intravenous Ferric Gluconate (Ferrlecit ^R) in Haemodialysis Patients. Nephrol Dial Transplant (1996) 11:820-824